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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,099	01/24/2002	Fu-Zon Chung	A0000247-01-DRK	1420

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/057,099

Applicant(s)

CHUNG ET AL.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,10,16,17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,10,16,17 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***1. Formal Matters***

- A. The Amendment filed 8/27/03, has been entered into the record.
- B. Claims 1-3, 5, 6, 10, 16 and 17 are pending. New claim 19 has been added. Therefore, claims 1-3, 5, 6, 10, 16, 17 and 19 are pending and are the subject of this Office Action.
- C. All Statutes not cited in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Claim Objections***

- A. All claim objections have been withdrawn in view of Applicants' amendments to or cancellation of the claims.
- B. Claim 1 is objected to since it recites "the NK receptor." There are more than one type of NK receptor. Applicants should amend the claim to recite "an NK receptor."

### ***3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement***

- A. Claims 1-3, 5, 6, 10, 16, 17 are rejected and new claim 19 is also rejected under 35 U.S.C. 112, first paragraph, for the reasons already of record on page 3 of the Office Action dated 3/27/03. Applicants argue that the specification is enabled for methods of detecting gabapentin activity using NK-expressing cells. Applicants provide support in the specification for the use of NK-expressing cells. However, this argument is not deemed persuasive.

Page 2 of the specification states that "NK expressing cells are stimulated with substance P which results in the phosphorylation of the MAP kinase member. Erk-2...To screen for gabapentinoid activity, test substances are individually incubated with the activated cells and Erk-2 phosphorylation determined. In preferred embodiments. Erk-2 phosphorylation after treatment with a test compound is compared to activated cells treated with a similar concentration of gabapentin." However, the concern of the Examiner is how it can be concluded, respectfully, that simply determining the effect of a test compound on Erk-2 expression is indicative of a compound having gabapentinoid activity. As stated in the previous Office Action:

"Applicants have provided no guidance or working examples of any compounds other than gabapentin which have the intended in vivo effects, nor have Applicants taught how measuring Erk-2 activation is indicative of a compound possessing gabapentin activity, as gabapentin is not the only

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compound which acts via Erk-2 activation. Furthermore, it would not be predictable to one of ordinary skill in the art that a compound which activates Erk-2 would have gabapentin activity since the mechanism of action of gabapentin is unusual, as it would be predicted that most anticonvulsants act via GABA receptors. Therefore, identifying a compound which acts through a distinct, unexpected, pathway to produce anticonvulsant effects would, respectfully, require more than just realizing that the compound activates Erk-2.

Therefore, due to this lack of guidance and working examples of compounds having gabapentin activity which act via Erk-2 activation as well as the inability to predict that compounds, other than gabapentin, which act via Erk-2 would, in fact, have gabapentin activity, leads the Examiner to conclude that undue experimentation would be required to practice the invention as claimed.”

Therefore, clarification of this issue is respectfully requested.

B. The rejection of claims 1-3, 5, 6, 10, 16 and 17 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants’ amendment to the claim to recite that the cells express NK receptors.

C. Claim 1-3, 5, 6, 10, 16, 17 and 19 are rejected under 35 USC 112, first paragraph, since there appears to be a conflict between independent claims 1 and 16. Claim 1 does not require that the cells must over-express NK-1. The kit of claim 16 does require this limitation. Therefore, in reading claim 16, it appears that Applicants are only enabled for methods in which the cells over-express NK-1 receptors, or possibly NK receptors in general. Clarification of this issue is respectfully requested.

#### ***4. Claim Rejections - 35 USC § 112, second paragraph***

A. Claims 1-3, 5, 6 and 10 remain rejected and new claim 19 is also rejected for the reasons already of record on page 5 of the Office Action dated 3/27/03 regarding the requirement of a method step. Applicants have amended the claims to recite the use of NK-expressing cells. However, Applicants argue that they are not aware of a requirement for a conclusion step. The issue is that the preamble of claims 1 and 19 recite a method for detecting gabapentinoid activity in a compound. However, nothing in the claim requires that gabapentinoid activity be detected. The claims only require the comparison of reporter gene activity and do not provide any requirement that this reporter gene be indicative of gabapentinoid activity, as discussed in paragraph A of the rejection under 35 USC 112, first paragraph. Respectfully, one cannot conclude that observing reporter gene activity indicates that a compound has gabapentinoid activity.

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B. Claims 1-3, 5, 6, 10, 16, 17 and 19 are rejected under 35 USC 112, second paragraph, since it is not clear what the "target compound" represents. In other words it is not clear what is being targeted. It appears that this compound should be referred to as, for example, a "test compound" – as long as this term is supported in the specification.

C. Claims 1-3, 5, ~~10~~ and ~~19~~ are rejected under 35 USC 112, second paragraph, since it is not clear what the purpose is in using "at least two groups" or a "plurality" of groups. No steps have been recited in order to clearly explain how to use more than two groups.

D. Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the contents of the kit other than a cell line which over-expresses the NK-1 receptor. It is not understood how the artisan can use a kit comprising only cells.

#### **5. Prior Art**

A. The Examiner agrees with Applicants' statement regarding the novelty and unobviousness of the claimed methods.

#### **6. Conclusion**

A. No claim is allowable.

#### **Advisory information**

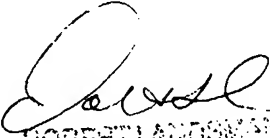
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
November 04, 2003



ROBERT LANDSMAN  
PATENT EXAMINER